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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,643	08/21/2003	Adrian Liem	4-32682A	8789

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/645,643	Applicant(s) LIEM ET AL.	
	Examiner Vanessa L. Ford	Art Unit 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 January 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: *NONE*.
   Claim(s) rejected: *21 and 22*.
   Claim(s) withdrawn from consideration: *NONE*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see Advisory attachment.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: Advisory attachment.

Advisory Attachment

1. Applicants amendment filed January 12, 2006 is acknowledged.

Rejections Maintained

2. The rejection under 35 U.S.C. 103(a) over claims 21-22 is maintained for the reasons set forth pages 3-5 paragraph 5 of the Final Office Action.

The rejection was on the grounds that Garcia et al teach a method of preventing liver abscesses in bovines (see the Abstract). Garcia et al teach the *Sphaerophous necrophorus* was isolated from bovine (page 223). Garcia et al teach that the *S. necrophorus* preparations used to make the vaccine compositions were treated (inactivated) using formaldehyde (page 223). Garcia et al teach that the vaccine composition was formulated using alum (page 223). Garcia et al teach that the antigen suspension was adjusted to 1 mg/ml protein (page 223). Garcia et al teach that the doses range form 1.0 to 20.0 ml (page 223). Garcia et al teach that calves were injected subcutaneously in the neck (page 223). Garcia et al teach that claves were given an initial dose of the vaccine and received a booster injection of dose 0.1 mg/ml protein in 5.0 ml of saline (page 224). Garcia et al teach that the vaccine composition comprising *S. necrophorus* cytoplasmic toxoid was the most effective in protecting against liver abscesses due to *S. necrophorus* infection (page 225).

Garcia et al do not teach preventing footrot.

Emery et al teach that the gram-negative *Fusobacterium necroporum* causes foot abscesses and live abscesses in ruminants (page 43). Emery et al teach that *Fusobacterium necrophorum* can be cultured on suitable medium for a period of time up to 18 hours (page 44). Therefore, the prior art teaches the claim limitation "...successive generations in a suitable growth medium for a period of time equal to between 10 hours and 18 hours to form an *Fusobacterium necrophorum* bacteria whole cell culture, with said bacteria culture" is taught by the prior art.

It would be *prima facie* obvious at the time the invention was made to use a vaccine composition comprising *Fusobacterium necrophorum* in a method of preventing footrot or liver abscesses because Emery et al teach that the association between *Fusobacterium necrophorum* specifically, the strain of biotype AB and lesion of foot abscesses in cattle implies that potential vaccine against infection should be sought from these strains of *F. necrophorum* (page 46). It would expected barring evidence to the contrary that vaccine composition comprising *Fusobacterium necrophorum* would be effective in preventing infections caused by *F. necrophorum* because Garcia et al has shown that *F. necrophorum* is effective against preventing *F. necrophorum* infections.

Applicant's arguments

A) Applicant urges that Garcia et al do not teach "whole cell cultures" to prepare the vaccines used in the method of preventing footrot and liver abscesses in bovines.

B) Applicant urges that Garcia et al teach away from the used of whole cultures in the vaccine compositions used in the claimed and one skill in the art would not recognize that Garcia et al teach vaccine compositions prepared from whole cell cultures.

C) Applicant urges that Emery et al do not provide any remedy for the failure on the part of Garcia.

Examiner's Response to Applicant's Arguments

A) It is the Examiner's position that Garcia et al teach that certain vaccine compositions used in the invention were prepared from sonicated, unfractionated cells (whole cells) (page 223, 2nd column). Therefore, one of skill in the art would recognize that Garcia et al teach that vaccines used in the method were prepared using whole cell cultures.

B) It is the Examiner's position that the combination of references teach the claimed invention. Thus, the combination of references do not teach away from the claimed invention.

C) It should be remembered that it is the combination of references that teach the claimed invention. Thus, Emery et al teach that *Fusobacterium necroporum* causes foot abscesses and live abscesses in ruminants. Therefore, this reference established a nexus between *Fusobacterium necroporum* and foot abscesses in ruminants. It is the Examiner's position that there is nothing on the record to suggest that the combination of references do not teach the claimed invention.

3. The rejection under 35 U.S.C. 103(a) over claims 21-22 is maintained for the reasons set forth pages 6-8 paragraph 6 of the Final Office Action.

The rejection was on the grounds that Garcia et al teach a method of preventing liver abscesses in bovines (see the Abstract). Garcia et al teach the *Sphaerophous necrophorus* was isolated from bovine (page 223). Garcia et al teach that the *S. necrophorus* preparations used to make the vaccine compositions were treated (inactivated) using formaldehyde (page 223). Garcia et al teach that the vaccine composition was formulated using alum (page 223). Garcia et al teach that the antigen suspension was adjusted to 1 mg/ml protein (page 223). Garcia et al teach that the doses range form 1.0 to 20.0 ml (page 223). Garcia et al teach that calves were injected subcutaneously in the neck (page 223). Garcia et al teach that claves were given an initial dose of the vaccine and received a booster injection of dose 0.1 mg/ml protein in 5.0 ml of saline (page 224). Garcia et al teach that the vaccine composition comprising *S. necrophorus* cytoplasmic toxoid was the most effective in protecting against liver abscesses due to *S. necrophorus* infection (page 225).

Garcia et al do not teach preventing footrot.

Clark et al teach that *Fusobacterium necrophorum* is effective in preventing interdigital necrobacillosis (footrot) (see the Abstract). Clark et al teach that vaccine compositions contained whole cultures, cytoplasmic fractions, cell-free supernatants or killed cells formulated in a mineral oil adjuvant (page 107-108). Clark et al teach that vaccine compositions comprising culture supernatants provided the most protection against footrot in cattle (see the Abstract and page 109). Clark et al teach that *Fusobacterium necrophorum* can be cultured on suitable medium for a period of time up to 18 hours (page 107). Therefore, the prior art teaches the claim limitation "...successive generations in a suitable growth medium for a period of time equal to between 10 hours and 18 hours to form an *Fusobacterium necrophorum* bacteria whole cell culture, with said bacteria culture" is taught by the prior art.

It would be *prima facie* obvious at the time the invention was made to add the vaccine compositions comprising culture supernatants of *Fusobacterium necrophorum* as taught by Clark et al to the vaccine compositions comprising *Fusobacterium necrophorum* cytoplasmic toxoid of Garcia et al to be used to prevent footrot and liver abscesses in cattle because Garcia et al has demonstrated that compositions comprising *F. necrophorum* cytoplasmic toxoid are effective at preventing liver abscesses in cattle and Clark et al has demonstrated that compositions comprising *F. necrophorum* culture supernatants are effective in preventing footrot in cattle. It would expected barring evidence to the contrary that vaccine compositions comprising *F. necrophorum* cytoplasmic toxoid and culture supernatants would be effective in preventing infections caused by *F. necrophorum*.

Applicant's arguments

A) Applicant urges that Garcia et al do not teach "whole cell cultures" to prepare the vaccines used in the method of preventing footrot and liver abscesses in bovines.

B) Applicant urges that Garcia et al teach away from the used of whole cultures in the vaccine compositions used in the claimed and one skill in the art would not recognize that Garcia et al teach vaccine compositions prepared from whole cell cultures.

C) Applicant urges that Clark et al do not provide any remedy for the failure on the part of Garcia.

Examiner's Response to Applicant's Arguments

A) To address Applicant comments regarding Garcia et al, Garcia et al teach that certain vaccine compositions used in the invention were prepared from sonicated, unfractionated cells (whole cells) (page 223, 2nd column). Therefore, one of skill in the art would recognize that Garcia et al teach that vaccines used in the method were prepared using whole cell cultures.

B) Garcia et al and Clark et al both teach vaccine compositions comprising whole cell cultures. Thus, the combination of references do not teach away from the claimed invention.

C) It should be remembered that Clark et al teach vaccine compositions comprising *Fusobacterium necroporum* whole cell cultures (page 107, 2nd column). Clark et al teach also teach that *Fusobacterium necroporum* causes interdigital necrobacillosis Thus, this reference established a nexus between *Fusobacterium necroporum* and interdigital necrobacillosis in cattle. It should be noted that Clark et al teach that group 1 was immunized with vaccines comprising whole cell cultures and provided protection against interdigital necrobacillosis (page 109, 2nd column). It is the Examiner's position that there is nothing on the record to suggest that the combination of references do not teach the claimed invention.

Response to Potential Art Rejection

4. This matter was discussed with the supervisory patent examiner and a tech center specialist and it appears that this matter does not impact the prosecution of this application since the claims in this application are directed to a method of using the *Fusobacterium necroporum* vaccine compositions

Status of Claims

5. No claims are allowed.

Conclusion

6. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
February 28, 2006

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600